

### ***Remarks***

#### ***Support for the Amendments***

By the foregoing amendments, claims 39-41, 43-45, 47, 52, 58-60, 62, 69, 72, 101, 104, 107 and 110 are sought to be amended, and claims 55-57, 89 and 94 have been canceled without prejudice or disclaimer. Support for the foregoing amendments to the claims can be found throughout the specification, specifically at pages 17-31 and throughout the Figures and Examples. Therefore, these amendments do not add new matter, and their entry and consideration are respectfully requested.

#### ***Status of the Claims***

By the foregoing amendments, claims 39-41, 43-45, 47, 52, 58-60, 62, 69, 72, 101, 104, 107 and 110 are sought to be amended, and claims 55-57, 89 and 94 have been canceled without prejudice or disclaimer. Upon entry of the foregoing amendments, claims 35-36, 38-54, 58-66, 69-75, 77, 79-88, 90-93 and 95-112 are pending in the application, with claims 35, 39, 52, 69 and 72 being the independent claims.

#### ***Summary of the Office Action***

In the Office Action dated April 28, 2005, the Examiner has made six rejections of the claims. Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

***The Rejections Under 35 U.S.C. § 112, Second Paragraph***

In the Office Action at pages 3-6, the Examiner has rejected claims 39-66, 79-96 and 101-106 under 35 U.S.C. § 112, second paragraph, alleging that that terms "recombination site" and "cloning site" are vague and indefinite. Applicants respectfully traverse this rejection. However, solely to expedite prosecution, and not in acquiescence to this rejection, claims 55-57, 89 and 94 have been cancelled. Hence, the portion of this rejection that may have applied to these claims has been rendered moot. Applicants also respectfully traverse this rejection as it may apply to the remaining claims.

As noted in Applicants' previous reply filed January 24, 2005, and incorporated by reference herein in its entirety, Applicants submit that the ordinarily skilled artisan, guided by the present specification, would have readily understood that the term "recombination site" refers to site-specific recombination sites. However, solely to expedite prosecution, and not in acquiescence to this rejection, Applicants have revised this term in the present claims to recite "site-specific recombination site," thereby making explicit that which was at least implicit in the claims as previously presented.

The Examiner also asserts that the dependent claims drawn to nucleic acids comprising specific site-specific recombination sequences (e.g., *loxP*) are vague and indefinite, because such nucleic acids may contain sequences at the recombination site in addition to the site-specific sequence. Applicants respectfully disagree with this assertion. As discussed in the previous reply, Applicants again submit that the ordinarily skilled artisan would readily understand that indeed, the nucleic acid molecules of the present invention can comprise, and often will comprise, nucleotide sequences at the recombination site in

addition to the site-specific recombination sequences. This fact though does not render the term "site-specific recombination site" vague or indefinite.

In view of the foregoing remarks, Applicants respectfully request that the rejection of claims 39-66, 79-96 and 101-106 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

The Examiner has also rejected claims 47 and 62 under 35 U.S.C. § 112, second paragraph, alleging that the term "one cloning site" is vague and indefinite, as it is unclear what the term encompasses. Applicants respectfully disagree with this allegation.

As discussed in the previous reply, Applicants respectfully submit that the ordinarily skilled artisan would readily understand that the term "one cloning site" encompasses any site within a given nucleic acid molecule which allows for insertion of a desired nucleic acid sequence. However, solely to expedite prosecution, and not in acquiescence to this rejection, Applicants have revised this term in the present claims to recite "multiple cloning site."

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 47 and 62 under 35 U.S.C. § 112, second paragraph.

***The Rejections Under 35 U.S.C. § 112, First Paragraph***

In the Office Action at pages 7-11, the Examiner has first rejected claims 52-66, 87-91 and 101-106 under 35 U.S.C. § 112, first paragraph, alleging that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had

possession of the claimed invention. Applicants respectfully traverse this rejection. However, solely to expedite prosecution, and not in acquiescence to this rejection, claims 55-57 and 89 have been cancelled. Hence, the portion of this rejection that may have applied to these claims has been rendered moot. Applicants also respectfully traverse this rejection as it may apply to the remaining claims.

The Examiner contends that the present specification does not provide sufficient basis for the ordinarily skilled artisan to envision embodiments of the claimed invention wherein the nucleic acid encoding a functional antibiotic resistance gene comprises a first portion and a second portion separated by any recombination site sequence. The Examiner further contends that in view of the present specification, the skilled artisan would not have been able to envision a sufficient number of specific embodiments to describe the broadly claimed genus of nucleic acids. The Examiner states that an applicant claiming a biotechnical invention cannot necessarily claim a genus after only describing a limited number of species. Applicants respectfully disagree with these contentions.

The presently claimed invention is directed to nucleic acid molecules, and host cells comprising these molecules, comprising various site-specific recombination sites in the recited orientations and combinations. The Examiner's attention is directed to the present specification at page 14, lines 1-15, where several non-limiting examples of such site-specific recombination sites are discussed. The Examiner's attention is also directed to page 22, line 15, through page 30, where numerous site-specific recombination systems are disclosed, including site-specific recombination proteins, recombination sites, and various mutated site-specific recombination sites which may be utilized in the practice of the presently claimed invention. Applicants respectfully submit that the ordinarily skilled

artisan would readily recognize that any of these site-specific recombination sites and systems can be successfully utilized in the practice of the presently claimed invention.

Applicants respectfully submit, as described in detail above and in Applicants' previous reply, the present specification provides disclosure of a great number of site-specific recombination sites that may be used in the practice of the present invention. Applicants respectfully submit that the ordinarily skilled artisan would readily recognize that any of these exemplary site-specific recombination sites can be used in the practice of the present invention, and hence, the ordinarily skilled artisan would easily be able to recognize a sufficient number of embodiments encompassed by the present invention.

In view of the foregoing remarks, Applicants respectfully request that the rejection of claims 52-68 and 87-91 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

In the Office Action at pages 11-13, the Examiner has next rejected claims 35-36, 38-66, 69-75 and 79-112 under 35 U.S.C. § 112, first paragraph, alleging that the phrase "immediately adjacent" does not have literal support in the specification. Applicants respectfully traverse this rejection. However, solely to expedite prosecution, and not in acquiescence to this rejection, claims 55-57, 89 and 94 have been cancelled. Hence, the portion of this rejection that may have applied to these claims has been rendered moot. Applicants also respectfully traverse this rejection as it may apply to the remaining claims.

As discussed in their previously reply, Applicants submit that Figure 4C clearly depicts an SP6 promoter located "immediately adjacent" to a *loxP* site. The ordinarily skilled artisan would readily understand that the orientation depicted in this figure represents a site-specific recombination site "immediately adjacent" to a promoter. The Examiner

states that, "in examining [Figure 4C] it is impossible to deduce whether the two structures are 'immediately adjacent' without any intervening sequence." Office Action at page 12, third paragraph, lines 3-5. The Examiner further states "[t]he limitation 'immediately adjacent' is interpreted to mean one structure is next to another structure, such as depicted in instant drawing 4C. However, the limitation is not interpreted to mean that there are no intervening sequences necessarily." Office Action at page 13, third paragraph, lines 1-3. Applicants agree with the Examiner's interpretation that Figure 4C is a representation of, and would be readily understood by the skilled artisan to represent, a promoter (SP6) "immediately adjacent" to a site-specific recombination site (*loxP*). However, in contrast with the Examiner's interpretation, Applicants respectfully submit that the term "immediately adjacent" would be readily understood to mean that there are no intervening nucleotides between the two structures.

Applicants submit, and as noted above, the Examiner has agreed, that Figure 4C schematically represents two structures that are "immediately adjacent" to one another, as that term is used in the present claims and specification (*see* Office Action at page 13, third paragraph, lines 1-3). The Examiner indicates that, without a sequence map of the vector depicted in Figure 4C, it is impossible to know whether intervening sequences are present. Office Action at page 12, fourth paragraph, lines 5-7. Applicants respectfully submit that, even in the absence of such a sequence map, the ordinarily skilled artisan would readily recognize that Figure 4C depicts an SP6 promoter immediately adjacent to a *loxP* site.

Figure 4C does not simply show one structure *next to* another structure as indicated by the Examiner (*see* Office Action at page 13, third paragraph, lines 1-3). Rather, it depicts an SP6 promoter *immediately adjacent to* a *loxP* site-specific recombination site, where there

are no intervening nucleotides between the two structures. The ordinarily skilled artisan, guided by the present specification, and specifically Figure 4C, would readily understand that the SP6 is "immediately adjacent" to the *loxP* site, with no intervening nucleotides, and not simply "next to" the *loxP* site.

Applicants respectfully submit that the Examiner's interpretation of a claim term must be consistent with that interpretation those skilled in the art would reach. *See In re Cortright*, 165 F.3d 1353 (Fed. Cir. 1999); *see also* M.P.E.P. § 2111 at 2100-47. Simply interpreting Figure 4C to mean that the SP6 promoter and the *loxP* site are "next to" one another, as the Examiner has indicated, is contrary to the purpose of the figure, which is to provide the ordinarily skilled with a detailed diagram of the spatial orientation of the various components of plasmid pEZC1003. The ordinarily skilled artisan would readily understand the detail provided in Figure 4C and would not consider the SP6 promoter to simply be "next to" the *loxP* site, but rather, would understand that these two structures are "immediately adjacent to" one another, with no intervening nucleotides, as shown in the figure. Applicants respectfully submit that the Examiner's interpretation of Figure 4C is inconsistent with the interpretation that those skilled in the art would reach, and thus the Examiner's interpretation of the phrase "immediately adjacent" is inconsistent with the interpretation that those skilled in the art would reach.

To provide further support for the interpretation Applicants submit would be consistent with the ordinarily skilled artisan, the Examiner is directed to page 38, lines 1-15 of the present specification. The schematic at lines 4-10, reproduced below, represents the nucleotide regions that participate in an *att* recombination reaction in *E. coli*.

attP--P1--H1--P2--X--H2--C-O-C'--H'--P'1--P'2--P'3--

+

attB --B-O-B'--

Int, IHF ↓ Xis, Int, IHF

attR --P1--H1--P2--X--H2--C-O-B'--

+

attL --B-O-C'--H'--P'1--P'2--P'3--

In describing this schematic, the present specification states that "O represents the 15 bp core DNA sequence found in both the phage and *E. coli* genomes; B and B' represent approximately 5 bases *adjacent* to the core in the *E. coli* genome;" (Specification at page 38, lines 11-13, emphasis added). Applicants respectfully submit that the ordinarily skilled artisan would readily understand, as stated, that B and B' are "adjacent" to the 15 bp core region "O," and as illustrated, have no intervening nucleotides between the core region, "O," and the 5 base pair B and B' regions (*i.e.*, no additional nucleic acids are shown in the schematic). The term "immediately" was added to the present claims to further clarify that two structures that are "adjacent" or "immediately adjacent" to one another are not simply "next to" one another, but rather are separated by no intervening nucleotides, as shown in the schematic above, and in Figure 4C as discussed above (as well as in Figures 8B, 8I and 8J).

The Examiner also states:

[f]urthermore, one is inclined to believe that that are intervening sequences considering that Applicants' reply controverts the assertion that no intervening sequences are present. For example, where Applicant states, "the nucleic acid molecules of the present invention can comprise, and often will



comprise, nucleotide sequences at the recombination site in addition to the site-specific recombination sites.

Office Action at page 12, fourth paragraph, lines 1-5 (citation omitted). Applicants respectfully disagree with the Examiner. In making this statement in their previous reply, Applicants were simply indicating that in certain situations, additional nucleic acid sequences can be present at the site-specific recombination site in addition to the sequence for the site-specific recombination site itself. For example, nucleic acids encoding a promoter element can be at the site of site-specific recombination site (*i.e.*, immediately adjacent to the site-specific recombination site). In other instances, nucleic acids encoding a portion of, or all of, an antibiotic resistance gene can be at the site of the site-specific recombination sites. Applicants respectfully submit that this statement in no way indicates that additional nucleotides can be present between two structures that are "immediately adjacent" to one another. It simply indicates that in addition to the site-specific recombination site, other nucleic acids encoding (or in some situations, not-encoding) other structures and genes of interest can also present at the site of (*i.e.*, immediately adjacent to) the site-specific recombination site.

In view of the foregoing remarks, Applicants respectfully submit that there is sufficient literal support for the phrase "immediately adjacent" in the present specification such that the ordinarily skilled artisan would readily understand this phrase as it is used in the present claims. Hence, Applicants submit that this term is not new matter, and that the present claims do comply with the written description requirement of 35 U.S.C § 112, first

paragraph. Therefore, reconsideration and withdrawal of the rejection of claims 35-36, 38-66, 69-75 and 79-112 are respectfully requested.

***The Rejections under 35 U.S.C. § 102(e) Over Wahl***

In the Office Action at pages 13-14, the Examiner has rejected claims 39, 43, 47-49, 52-54, 58, 62-64, 79, 81, 87-88, 90, 101-102 and 104-105 under 35 U.S.C. § 102(e), over Wahl *et al.*, U.S. Patent No. 5,677,177 (hereinafter "Wahl"). Applicants respectfully traverse this rejection.

The Examiner asserts that Wahl discloses a nucleic acid molecule comprising a promoter element (P or PSV) separated from an antibiotic resistance gene (NEO) by a site-specific recombination site (FLP target sites), where the FLP target site is immediately adjacent to the promoter or the antibiotic resistance gene. The Examiner therefore concludes that Wahl anticipates the present invention. Applicants respectfully disagree with the Examiner's conclusions and the assertions on which they are based.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984); *see also PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996) ("[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."). This burden is not met by Wahl.

Present claim 39 (and hence, claims 43, 47-49, 79, 81 and 101-102 that depend ultimately therefrom and that are also rejected over Wahl) recites a nucleic acid molecule

comprising at least one promoter operably linked to at least one antibiotic resistance gene, wherein the promoter and the antibiotic resistance gene are separated by at least one site-specific recombination site, and wherein the promoter is immediately adjacent to the at least one site-specific recombination site. Applicants respectfully submit that Wahl does not disclose a nucleic acid molecule comprising a promoter operably linked to an antibiotic resistance gene, and separated by a site-specific recombination site, wherein the promoter is also immediately adjacent to the site-specific recombination site. Wahl, specifically FIGs. 1A-1B, 2A and 3A, does not disclose a nucleic acid molecule where a promoter (P or PSV) is immediately adjacent to the site-specific recombination site (FRT sites indicated by block arrows) that separates the promoter from the antibiotic resistance gene.

As discussed above, the term "immediately adjacent," as it is used in the present claims and specification, indicates that there are no intervening nucleotides between two structures, in this case, between the promoter and the site-specific recombination site separating the promoter from the antibiotic resistance gene. The nucleic acids disclosed in Wahl clearly show the presence of intervening nucleotides between the promoter and the FRT site (block arrow). The plasmid pFRT $\beta$ GAL shown in FIG. 2A (and presumably represented in FIG. 1A) "contains a version of the bacterial  $\beta$ -galactosidase sequence modified by insertion of a FLP recombination target site, or FRT, within the protein coding sequence immediately 3' to the translation start." Wahl at column 9, lines 1-4. Thus, the PSV promoter indicated in FIGs. 1A and 2A is not immediately adjacent to the FRT site, as the FRT site is inserted *within* the  $\beta$ -gal coding sequence (i.e. downstream of translation start). Hence, there are intervening nucleotides between the PSV promoter and the FRT site-specific recombination site, and thus these two structures are not "immediately adjacent" to

one another, as recited in the present claims. Therefore, Wahl does not disclose every element of claim 39 (and hence, the dependent claims noted above), and under *Kalman*, cannot, and does not anticipate the presently claimed invention.

With regard to present claim 52 (and hence, claims 53-54, 58, 62-64, 87-88, 90 and 104-105, Applicants submit that the disclosure of Wahl is limited to the use of FRT site-specific recombination sites. Present claim 52, and hence the dependent claims noted above, recite the use of lambdoid *att* site-specific recombination sites, and mutants of such sites. Wahl does not disclose the use of such site-specific recombination sites, in any nucleic acid molecule, regardless of orientation. Hence, Wahl does not disclose every element of the present claims. Therefore, under *Kalman*, Wahl cannot and does not anticipate the presently claimed invention.

In view of the foregoing remarks, Applicants respectfully request that the rejection of claims 39, 43, 47-49, 52-54, 58, 62-64, 79, 81, 87-88, 90, 101-102 and 104-105 under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

***The Rejections under 35 U.S.C. § 102(e) Over Fukushima***

In the Office Action at pages 15-16, the Examiner has rejected claims 35-36, 38-49, 52-64, 69, 72, 75, 79-82, 87-91, 97, 99, 101-102, 104-105, 107-108 and 110-111 under 35 U.S.C. § 102(b), over Fukushima, S. and Sauer, B., *Proc. Natl. Acad. Sci.* 89:7905-7909 (1992) (hereinafter "Fukushima"). Applicants respectfully traverse this rejection. However, solely to expedite prosecution, and not in acquiescence to this rejection, claims 55-57 and 89 have been cancelled. Hence, the portion of this rejection that may have applied to these

claims has been rendered moot. Applicants also respectfully traverse this rejection as it may apply to the remaining claims.

The Examiner asserts that Fukushima discloses a nucleic acid molecule comprising a *loxP* site separating a promoter (CMV) from an antibiotic resistance gene (NEO), wherein the *loxP* site is immediately adjacent to the NEO gene. The Examiner therefore concludes that Fukushima anticipates the presently claimed invention. Applicants respectfully disagree with these assertions and the Examiner's conclusions.

Present claim 35 (and hence, claims 36, 38 and 75 that depend ultimately therefrom and are also rejected over Fukushima) recites a nucleic acid molecule comprising at least a first *lox* site located immediately adjacent to at least one promoter, wherein the promoter is operably linked to at least one antibiotic resistance gene. As noted above, the term "immediately adjacent" requires that no intervening nucleotides separate the first *lox* site and the promoter in the recited nucleic acid molecule. Applicants respectfully submit that Fukushima does not disclose such a nucleic acid molecule.

The nucleic acid molecule represented in FIG. 2 of Fukushima, and referred to by the Examiner, clearly has intervening nucleotides between the CMV promoter and the *loxP* site. A portion of the NEO gene (along with other nucleic acids) is clearly indicated (white box at the point of the arrow representing *loxP*) between the CMV promoter and the *loxP* site. As shown at the bottom of FIG. 2, the ATG start and several additional nucleotides are shown upstream of the *loxP* site. Further upstream, as represented in FIG. 1B, is the position of the CMV promoter. Hence, the CMV promoter is clearly not *immediately adjacent* to the *loxP* site, as at least 25 nucleotides separate the CMV promoter from the *loxP*

site. Hence, Fukushima does not disclose every element of present claim 35, and therefore under *Kalman*, cannot, and does not, anticipate the presently claimed invention.

As noted above, present claim 39 (and hence, claims 40-49, 79-82 and 101-102 that depend ultimately therefrom and that are also rejected over Fukushima) requires that the promoter is immediately adjacent to the site-specific recombination site separating it from the antibiotic resistance gene in the nucleic acid molecule. Applicants respectfully submit that Fukushima does not disclose a nucleic acid molecule comprising a promoter immediately adjacent to a site-specific recombination site that separates the promoter from an antibiotic resistance gene. The nucleic acid molecules disclosed in Fukushima clearly indicate the presence of intervening nucleotides between the CMV promoter and *loxP* site, and hence, these structures are not "immediately adjacent" to one another, as that term is used in the present claims and specification. Hence, Fukushima does not disclose every element of the present claim 39, and therefore under *Kalman* does not anticipate the presently claimed invention.

With regard to claim 52 (and hence, claims 53-54, 58-64, 87-88, 90-91 and 104-105 that depend ultimately therefrom and that are also rejected over Fukushima), Applicants submit that the disclosure of Fukushima is limited to the use of *loxP* site-specific recombination sites. As noted above, present claim 52, and hence the dependent claims noted above, are directed to lambdoid *att* site-specific recombination sites, and mutants of such sites. Fukushima does not disclose or enable the use lambdoid *att* sites in the nucleic acid molecule disclosed therein. Hence, Fukushima does not disclose every element of the present claims. Therefore, under *Kalman*, Fukushima cannot, and does not, anticipate the presently claimed invention.

Present claim 69 (and hence, claims 72, 97, 99 and 107-108 and 110-111 that depend ultimately therefrom and that are also rejected over Fukushima) recites a nucleic acid molecule comprising at least one promoter operably linked to at least one antibiotic resistance gene, wherein the promoter and the antibiotic resistance gene are separated by at least one *loxP* site, and wherein the promoter is immediately adjacent to the at least one *loxP* site. As discussed above, Fukushima does not disclose a nucleic acid molecule comprising a promoter immediately adjacent to at least one *loxP* site, as there are clearly intervening nucleic acid molecules between the CMV promoter and the *loxP* site disclosed in FIG. 2 of Fukushima. Hence, Fukushima does not disclose every element of the present claim 69, and therefore under *Kalman* does not anticipate the presently claimed invention.

In view of the foregoing remarks, and under *Kalman*, Applicants respectfully submit that Fukushima does not anticipate the presently claimed invention. Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C § 102(b) are respectfully requested.

***The Rejections under 35 U.S.C. § 103(a) Over Fukushima and Wahl and Further in View of Lenski***

In the Office Action at pages 16-18, the Examiner has rejected claims 35-36, 38-66, 69-75, 77 and 79-112 under 35 U.S.C. § 103(a), over Fukushima and Wahl and further in view of Lenski, R.E., *et al.*, *J. Bact.* 176:3140-3147 (1994). Applicants respectfully traverse this rejection. However, solely to expedite prosecution, and not in acquiescence to this rejection, claims 55-57, 89 and 94 have been cancelled. Hence, the portion of this rejection

that may have applied to these claims has been rendered moot. Applicants also respectfully traverse this rejection as it may apply to the remaining claims.

The Examiner states that Fukushima and Wahl do not explicitly disclose the use of chloramphenicol as an antibiotic resistance gene, or the use of bacterial host cells, such as *E. coli*. The Examiner relies on the disclosure Lenski to cure these deficiencies, asserting that it would have been obvious to use different antibiotic resistance genes in the practice of Fukushima and Wahl, and that it would have been obvious to use a bacterial cell, such as *E. coli*, in combination with these references as well. The Examiner therefore concludes that the present invention is rendered obvious in view of these references. Applicants respectfully disagree with this conclusion.

As noted above, Fukushima and Wahl are seriously deficient as primary references on which to base a *prima facie* case of obviousness, as neither reference discloses the recited nucleic acid molecules and host cells. Specifically, neither reference discloses a nucleic acid molecule comprising a promoter *immediately adjacent* to a site-specific recombination site that separates the promoter from an antibiotic resistance gene, and neither reference discloses or enables the use of lambdoid *att* sites. Applicants respectfully submit that, while Lenski may disclose the use of a chloramphenicol antibiotic resistance gene in combination with *E. coli* cells, Lenski does not disclose nucleic acid molecules comprising site-specific recombination sites (*lox* or lambdoid *att*). Furthermore, Lenski does not disclose nucleic acid molecules comprising a promoter immediately adjacent to a site-specific recombination site. Hence, Lenski does not cure the deficiencies in Fukushima and Wahl, and therefore cannot provide support for a *prima facie* case of obviousness.



In view of the foregoing remarks, Applicants respectfully submit that Fukushige, Wahl and Lenski, alone or in combination, do not render obvious the presently claimed invention. Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are respectfully requested.

***Other Matters***

In the Office Action at page 2, the Examiner has indicated that an English translation of two foreign language documents listed on Applicants' Sixth Supplemental Information Disclosure Statement, FR 2 670 502 (document AL20) and WO 92/10577 (document AM20), was not present in the record. Applicants respectfully submit that an English language abstract of these two documents was submitted as document AS213 with Applicants' Sixth Supplemental Information Disclosure Statement (IDS). In accordance with 37 C.F.R. § 1.98(a)(3) and M.P.E.P. § 609, this English language abstract was identified in Applicants' IDS pleading as providing a statement of the relevance of the two foreign language documents, AL20 and AM20. Applicants note that the Examiner has initialed and signed off next to document AS213 on page 14 of Form PTO-1449 submitted with Applicants' Sixth Supplemental Information Disclosure Statement, indicating that this English language abstract has been considered. Applicants respectfully request that the Examiner return a copy of page 1 of Form PTO-1449 indicating that references AL20 and AM20 have been considered, or otherwise indicate such with the Examiner's next correspondence.

The Examiner has also indicated that various links to internet sites listed on pages 2-3 of Form PTO-1449 of Applicants' Fourth Supplemental Information Disclosure Statement

were not considered as copies of the pages accessed were not provided. Applicants submit herewith copies of documents AR112, AS112, AT112, AR113 and AS113, along with a copy of the USPTO date-stamped post card indicating receipt by the USPTO of these documents. Applicants respectfully request that the Examiner return a copy of pages 2-3 of Form PTO-1449 indicating that these references have been considered, or otherwise indicate such with the Examiner's next correspondence.

***Conclusion***

All of the stated grounds of rejection have been properly traversed, rendered moot, or otherwise overcome. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn.

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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